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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,717	04/13/2000	Katsuya Daimon	472552000100	7198

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EXAMINER
CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
1637	18

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/548,717	DAIMON ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-24* is/are pending in the application.

4a) Of the above claim(s) *23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-22 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Acknowledgement is made for the request to establish continued prosecution application (RCE) (Paper NO. 17) filed on January 29, 2003. The request for RCE is accepted and is established with the status of the application as follows:

a. the filling date of this RCE is established as 4/13/2000;

b. Claims 1-7, 9-22 are pending. New claim 24 is added.

2. Applicants' response to the earlier office action (Paper No. 15) filed on 12/3/02 is reconsidered and has been entered.

Response to Arguments

3. Applicant's response to the office action (Paper No.15) is fully considered and found persuasive in view of arguments.

4. With reference to the rejection maintained in the previous office action under 35 U.S.C. 103(a), applicants' arguments and amendment have been fully considered and the rejection is moot in view of the new grounds of rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are dependent on a canceled claim and hence the meets and

bounds of the claims are unclear because it is indefinite whether the claims refer to a method which is not active or to an unkown method.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-7, 9-14, 19-20, 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Yamauchi et al. (USPN. 6,274,387).

With reference to the instant claim 1, Yamauchi et al. teach a method for isolating nucleic acids using silica-coated magnetic particles wherein Yamauchi et al. disclose that the method comprises

(a) mixing nucleic acid containing material with a nucleic acid- binding particulate carrier (silica coated magnetic particle) with a particle diameter of ranging from 1 to 200 um and more preferably ranging from 1 to 20 um, a pore diameter ranging from 1 to 100 nm, a pore

volume of 0.1 to about 2.5ml/g (see column 4, lines 6-47, column 5, lines 48-67, column 6, lines 1-14, column 13, lines 10-19);

(b) separating a composite of the nucleic acids and the particulate carrier from the mixture to remove contaminants (see column 13, lines 19-23);

(c) eluting and collecting the nucleic acids from the composite of the nucleic acids and the particulate carrier (see column 13, lines 23-30).

With reference to the instant claims 2-7, 9-14, 19-20, and 24, Yamauchi et al. also teach that the method comprises (i) the magnetic silica particulate carrier contains superparamagnetic metal oxide (see column 3, lines 49-60) and the metal oxide contained an amount of about 5 to about 50% by weight (see column 4, lines 62-64); (ii) a surface area of the particulate carrier ranges from 10 to 800 m^2 /g (see column 6, lines 15-22); (iii) the nucleic acids comprises DNA , and /or RNA, and the nucleic aicds containing biological material include body fluids (serum of HCV-infected persons) (see column 16, lines 15-18); (iv) the method contains extraction of nucleic acids with wash solutions containing chaotropic substance (guanidine thiocyanate) and alcohol (40% isopropanol) (see column 16, lines 19-55); (v) the method further includes the detection of target nucleic acid comprising extracting the nucleic acids and amplifying the target nucleic acid by polymerase chain reaction (PCR) (see column 13, lines 14-50, column 16, lines 19-60); (vi) nucleic acids bind to the silica particulate via hydrogen bonds between hydroxyl groups on the particle surfaces of the carrier (silanol group, Si-OH) (see column 8, lines 52-55). Thus the disclosure of Yamauchi et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-18, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamauchi et al. (USPN. 6,274,387) and in view of Uematsu et al. (USPN. 5,945,525).

Yamauchi et al. teach a method for isolating nucleic acids using silica-coated magnetic particles wherein Yamauchi et al. disclose that the method comprises

(a) mixing nucleic acid containing material with a nucleic acid- binding particulate carrier (silica coated magnetic particle) with a particle diameter of ranging from 1 to 200 um and more preferably ranging from 1 to 20 um, a pore diameter ranging from 1 to 100 nm, a pore volume of 0.1 to about 2.5ml/g (see column 4, lines 6-47, column 5, lines 48-67, column 6, lines 1-14, column 13, lines 10-19);

(b) separating a composite of the nucleic acids and the particulate carrier from the mixture to remove contaminants (see column 13, lines 19-23);

(c) eluting and collecting the nucleic acids from the composite of the nucleic acids and the particulate carrier (see column 13, lines 23-30).

Yamauchi et al. also teach that the method comprises (i) the magnetic silica particulate carrier contains superparamagnetic metal oxide (see column 3, lines 49-60) and the metal oxide contained an amount of about 5 to about 50% by weight (see column 4, lines 62-64); (ii) a surface area of the particulate carrier ranges from 10 to 800 m^2 /g (see column 6, lines 15-22); (iii) the nucleic acids comprises DNA, and /or RNA, and the nucleic acids containing biological material include body fluids (serum of HCV-infected persons) (see column 16, lines 15-18); (iv) the method contains extraction of nucleic acids with wash solutions containing chaotropic substance (guanidine thiocyanate) and alcohol (40% isopropanol) (see column 16, lines 19-55); (vii) the method further includes the detection of target nucleic acid comprising extracting the nucleic acids and amplifying the target nucleic acid by polymerase chain reaction (PCR) (see column 13, lines 14-50, column 16, lines 19-60); nucleic acids bind to the silica particulate via hydrogen bonds between hydroxyl groups on the particle surfaces of the carrier (silanol group, Si-OH) (see column 8, lines 52-55). Thus the disclosure of Yamauchi et al. meets the limitations in the instant claims. However, Yamauchi et al. did not specifically teach washing with guanidine thiocyanate and ethanol and detection of nucleic acid by using nucleic acid sequence based amplification (NASBA) and hybridization assay.

Uematsu et al. teach a method for extracting nucleic acids wherein Uematsu et al. disclose that the method comprises (i) first wash buffer containing guanidine thiocyanate and second wash buffer containing ethanol (70%) (see column 8, lines 24-46); (ii) the method further includes the detection of target nucleic acid comprising extracting the nucleic acids and

amplifying the target nucleic acid by polymerase chain reaction (PCR) or nucleic acid sequence based amplification (NASBA) and detecting the target by nucleic acid hybridization assay (see column 8, lines 57-67 and column 9, lines 1-10).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of extracting nucleic acids as taught by Yamauchi et al. with the method as taught by Uematsu et al. which is applicable to purification of nucleic acids because Uematsu et al. states that 'for the purposes of purification of nucleic acids wash buffers include chaotropic material and ethanol" (see column 7, lines 20-50). An ordinary practitioner would have been motivated to combine the method of Yamauchi et al. with the method of Uematsu et al in order to achieve the expected advantage of developing a method to enhance quality of isolated of nucleic acids.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
February 21, 2003

JEFFREY FREDMAN
PRIMARY EXAMINER